

TITLE 22. EMERGENCY MEDICAL SERVICES AUTHORITY NOTICE OF PROPOSED RULEMAKING

Notice is hereby given that the Emergency Medical Services Authority (EMS Authority) is proposing to adopt, amend and repeal regulations in Sections 100031 through 100041, Chapter 1.8, Division 9, Title 22 of the California Code of Regulations [CCR]. These regulations specify training, medical control, operational, and authorization standards for use of the automated external defibrillator (AED) by non-license or non-certified personnel (Layperson).

WRITTEN COMMENTS AND AGENCY CONTACT

Interested persons are invited to submit written comments on the proposed regulatory action. A 45-day written comment period is provided from September 14, 2001 through October 29, 2001. The written comment period closes at 5:00 p.m. on October 29, 2001, and comments received after this date will not be accepted. The rulemaking file for the proposed regulatory action is available for review from 9:00 a.m. until 4:00 p.m., Monday through Friday, at the EMS Authority located at 1930-9th Street, Sacramento, California. To schedule a review of the rulemaking file, submit written comments, or obtain answers to questions on the substance of the regulations, contact the following person:

Primary Contact:

Sean Trask
Basic Life Support Coordinator
EMS Authority
1930 9th Street
Sacramento, CA 95814
e-mail: sean.trask@emsa.ca.gov
Phone: (916) 322-4336
Fax: (916) 324-2875

Alternate Contact:

Lois Williams
(916) 322-4336

PUBLIC HEARING

The EMS Authority will hold a public hearing to permit all interested parties the opportunity to present statements, arguments, written materials, or contentions relevant to the regulatory action. The public hearing will be held on:

Date: October 29, 2001
Time: 9:00 a.m. to 12:00 p.m.
Location: EMS Authority, 1930 9th Street, Sacramento, CA 95814

The facility to be used for the public hearing is accessible to persons with mobility impairments. Persons with sight or hearing impairments are asked to write Sean Trask at the address above or call Mr. Trask at (916) 322-4336 to make special arrangements, if necessary.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons and other information will be available on the EMS Authority website at www.emsa.ca.gov, at the office of the EMS Authority at the address listed above and at the public hearing noted above. Copies may be obtained by contacting either Sean Trask or Lois Williams at the address or phone number listed above.

AUTHORITY AND REFERENCE

The EMS Authority is proposing this regulatory action pursuant to the authority vested by Sections 1797.107, 1797.190 and 1797.196 of the Health and Safety Code (H&SC) and Section 1714.21 of the California Civil Code.

Section 1797.107 requires the EMS Authority, upon approval of the Commission on Emergency Medical Services, to adopt, amend, or repeal regulations to carry out the provisions of Division 2.5 of the H&SC.

Section 1797.190 states that the EMS Authority may establish minimum standards for the training and use of automatic external defibrillators.

Section 1797.196 establishes training, use, placement requirements, maintenance and readiness checks for AED users.

The proposed regulatory action will implement, interpret or make specific Section 1797.170 of the Health and Safety Code.

Section 1714.21 of the California Civil Code provides protection from liability from civil damages when a person complies with the regulations adopted by the EMS Authority and the American Heart Association or the American Red Cross for CPR and AED use.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Current regulations in Division 9 of Title 22 establish the minimum training, medical control and authorization standards for the lay public to use an AED.

These proposed regulations are intended to reduce the burden of initial training and continued training and competency of laypersons authorized to use the AED.

The proposed amendments to Sections 100031 through 100041 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allows the EMS Authority to adopt regulations by adding Section 1797.196 to each reference section of each section of this chapter. Section 1797.196 was added to the Health and Safety Code in 1999 as a result of Senate Bill (SB) 911.

The proposed amendments to Section 100031 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend regulations to improve the clarity of the section in plain language.

The proposed amendments to Section 100032 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend the definition of an AED that is current with the technological advances of AED devices.

The proposed amendments to Section 100033 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend the definition of cardiopulmonary resuscitation to include maneuvers for relief of foreign body airway obstructions since foreign body airway obstruction is a contributing factor of cardiac arrest and must be relieved before a person can be successfully resuscitated.

The proposed amendments to Section 100036 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to adopt, in the reference section, Section 1797.189 of Division 2.5 of the H&SC that pertains to the descriptions of prehospital emergency medical care personnel. Section 1797.189 of the H&SC was referenced in Section 100036(b) of the previous version of regulations, but not in the statutory reference section.

The proposed amendments to Section 100037 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to eliminate the prior CPR training as an eligibility requirement for AED training. Many national organizations such as the AHA, the American Red Cross and the National Safety Council have combined CPR and AED training into one course. Organizations that implement AED programs will be able to complete the entire training in one session instead of requiring CPR training first, demonstrating proficiency in CPR and then completing AED training, thereby making the initial training less burdensome and more efficient.

The proposed amendments to Section 100038 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to renumber the section.

The proposed amendments to Section 100038 of Title 22, Subsection (a) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend the section to indicate that a person may apply prior CPR training for AED training if that person is able to verify CPR training.

The proposed amendments to Section 100038 of Title 22, Subsection (b) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to repeal the requirement that AED training needs to be presented over two sessions preferably over at least two days and add that the training may be combined with a CPR course. AED training is commonly offered in one course and is combined with a CPR course by national organizations such as the AHA, American Red Cross and the National Safety Council.

The proposed amendments to Section 100038 of Title 22, Subsection (b)(2)(D) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to add the term, “adequate airway care” because this is a standard topic in CPR courses. The acronym “ABC”, that is commonly taught in CPR courses, refers to airway, breathing and circulation. Airway is the first in the sequence because it is the most important and without an adequate airway the patient has little if any chance of survival.

The proposed amendments to Section 100038 of Title 22, Subsection (b)(2)(E) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to:

1. Renumber the subsection, and
2. Add the term, “if applicable” to the internal emergency response system topic of the initial training. Not all authorized AED providers will be part of an internal emergency response system. Internal response systems may be established in areas with a large number of employees such as factories, warehouses and large office complexes.

The proposed amendments to Section 100038 of Title 22, Subsection (b)(4) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to add the phrase, “to include evaluation of airway, breathing and circulation” was added to the minimum training topics because this is an important part of the assessment of an unconscious patient and is part of the AHA Guidelines.

The proposed amendments to Section 100038 of Title 22, Subsection (b)(5)(A-D) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to add the listed safety precautions (age and weight restrictions, presence of water or liquid on or around the victim, presence of transdermal medications, implantable pacemakers or automatic implantable cardioverter-defibrillators) to the minimum training topics because they specify circumstances when the device should not be used and other circumstances where the victim, the operator and other rescuers safety may be at risk. These safety precautions are also listed in the AHA guidelines.

The proposed amendments to Section 100038 of Title 22, Subsection (b)(8) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend regulations to improve the clarity of the section in plain language.

The proposed amendments to Section 100039 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to renumber this subsection to 100038.

The proposed amendments to Section 100039 of Title 22, Subsection (a)(1) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to amend regulations to improve the clarity of the section in plain language.

The proposed amendments to Section 100039 of Title 22, Subsection (a)(4) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to reduce the periodic training and skill proficiency demonstration requirement from quarterly to annually. Advances in AED technology have reduced the need for quarterly training and proficiency demonstrations. AED devices prompt the user to complete each step of the process to apply the device and administer a shock to a cardiac arrest victim.

The proposed amendments to Section 100040 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to renumber this subsection to 100039.

The proposed amendments to Section 100041 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to renumber this subsection to 100040.

The proposed adoption of Article 5 to Chapter 1.8 of Title 22 will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to adopt a new article for operational requirements of AED providers. The operational requirements did not fit in an existing article; therefore, a new article was created.

The proposed adoption of Section 100041 of Title 22, Subsections (a) through (e) will implement and make specific H&SC Sections 1797.107 and 1797.190, which allow the EMS Authority to adopt operational requirements that are specified in Section 1797.196 of the H&SC. Section 1797.196 of the Health and Safety Code was enacted in 1999 from SB 911 and requires the AED provider to: notify the local EMS agency of the existence, type and location of AED acquired; conduct regular maintenance, tests and checks for readiness; ensure that the EMS system is activated when an AED is used on a cardiac arrest victim; and ensure that a physician, licensed in California, is involved in developing the AED program and complying with these regulations.

MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS

The EMS Authority has determined that this regulatory action does not impose a mandate on local agencies or school districts.

ASSESSMENT STATEMENT

The EMS Authority has determined that the proposed regulatory action will not create or eliminate jobs in California, will not create new business or eliminate existing businesses within California, and will not affect the expansion of businesses currently doing business in California.

EFFECT ON HOUSING COSTS

The EMS Authority has made an initial determination that this proposed regulatory action will have no fiscal impact on housing costs.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS

The EMS Authority has determined that there could be a financial impact on a private person as a result of the proposed regulatory action. The financial impact associated with the proposed regulatory action may consist of the cost of an AED, the initial training, on-going training, textbooks and school supplies. There could also be a financial impact on business with respect to paying for an employee to attend training and any of the related costs, as well as scheduling time off and shift coverage for the employee. There could be a cost savings for those AED programs that are currently established by reducing the periodic training and skill proficiency demonstrations from quarterly to annually.

ADVERSE ECONOMIC IMPACT ON BUSINESS

The EMS Authority has also made an initial determination that the proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

IMPACT ON SMALL BUSINESS

The EMS Authority has determined that the proposed amendments to the regulations may affect small business by resulting in a cost savings by reducing the periodic training and skill proficiency demonstrations from quarterly to annually for those AED programs that are established.

FEDERAL FUNDING TO THE STATE

The proposed amendments to the regulations will not result in any costs or savings in federal funding to the state.

NON-DISCRETIONARY COSTS OR SAVINGS

The proposed amendments to the regulations will not impose any non-discretionary costs on, or provide any non-discretionary savings to, local agencies.

COSTS OR SAVINGS TO STATE AGENCIES

There will be no additional costs or savings to the EMS Authority or any other state agencies as a result of this proposed regulatory action.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subsection (a)(13), the EMS Authority must determine that no reasonable alternative considered by the EMS Authority, or that has otherwise been identified and brought to the attention of the EMS Authority, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action. Therefore, the EMS Authority invites interested persons to present statements or arguments during the public comment period or at the public hearing noted above with respect to alternatives to the proposed regulations.

FINAL STATEMENT OF REASONS

Following the public hearing, the Commission on the Emergency Medical Services may approve for adoption the proposed revisions to the Training Standards for Use of the Automated External Defibrillator by Non-Licensed or Non-Certified Personnel as described in this notice. If approved, copies of the regulations as finally adopted will be sent to all persons on the EMS Authority's mailing list. In addition, a copy of the Final Statement of Reasons will be available on the EMS Authority's website, www.emsa.ca.gov, or by calling or writing the EMS Authority's contacts as identified in this notice.

However, if as a result of public comment (oral or written), substantial changes to the regulations are deemed appropriate, copies of the changes will be sent to all persons on the EMS Authority's mailing list, all persons who testified at the public hearing or who submitted written comments during the comment period or at the public hearing, and to those who have requested copies of information regarding the regulation revisions. The EMS Authority will then accept written comments, arguments, or evidence for a period of at least 15 days after the date on which the changes were made available.